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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/837,446	04/17/2001	Eugene C. Butcher	STAN110CON	4334

7590 04/22/2002
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EXAMINER

ROARK, JESSICA H

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 04/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/837,446

Applicant(s)

BUTCHER ET AL.

Examiner

Jessica H. Roark

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1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.

- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Sequence Compliance

1. The instant application appears to be in sequence compliance for patent applications containing nucleotide sequence and/or amino acid sequence disclosures.

Restriction Requirement

2. Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

3. The following is noted:
Independent Claims 1 and 13 broadly recite methods of "modulating" which encompasses administering "agents" that are either "agonist" or "antagonists". Page 5 of the specification indicates that "agonists" are administered to attract systemic memory T cells (i.e. to stimulate cell trafficking), whereas "antagonists" are administered to block trafficking of systemic memory T cells. Thus a recitation of "modulating" encompasses two mutually exclusive methods.

In addition, dependent claim 9 recites two "agonists" that do not share *a substantial structural feature essential to a common utility*. Dependent claims 21 and 22 recite individual antibody "antagonists" that do not share *a substantial structural feature essential to a common utility*. Individual antagonists and agonists that do not share *a substantial structural feature essential to a common utility* are subject to restriction, rather than election of species (as per MPEP 803.02), within the context of the particular method.

The restriction has therefore been set forth for the methods encompassing each recited structurally distinct antagonist agent and each recited structurally distinct agonist agent as separate groups, irrespective of the format of the claims.

Finally, it is noted that many other structurally distinct products are encompassed by the term "agent". If claims are introduced during the course of prosecution that recite other "agents" which lack a substantial structural feature essential to a common utility, then a supplemental restriction requirement may be issued.

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4. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-9 and 13-17, drawn to a method of attracting systemic memory T cells by administering an **agonist agent that is TARC**, classified in Class 424, subclass 85.1.

II. Claims 1-9 and 13-17, drawn to a method of attracting systemic memory T cells by administering an **agonist agent that is MDC**, classified in Class 424, subclass 85.1.

III. Claims 1-7 and 10-21, drawn to a method of blocking trafficking of systemic memory T cells by administering an **antagonist agent that is an antibody to CCR4**, classified in Class 424, subclass 143.1.

IV. Claims 1-7, 10-20 and 22, drawn to a method of blocking trafficking of systemic memory T cells by administering an **antagonist agent that is an antibody to the CCR4 ligand TARC**, classified in Class 424, subclass 145.1.

V. Claims 1-7, 10-20 and 22, drawn to a method of blocking trafficking of systemic memory T cells by administering an **antagonist agent that is an antibody to the CCR4 ligand MDC**, classified in Class 424, subclass 145.1.

5. Groups I-V are different methods. As noted supra, each method differs with respect to one or more of the ingredients administered, method steps, patient populations and/or endpoints; therefore, each method is patentably distinct.

6. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products administered and the various methods of use comprising distinct method steps which reach different endpoints. Therefore restriction for examination purposes as indicated is proper.

7. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica Roark whose telephone number is (703) 605-1209. The examiner can normally be reached Monday through Friday from 8:00 AM to 4:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Jessica Roark, Ph.D.
Patent Examiner
Technology Center 1600
April 22, 2002

PHILLIP GAMBEL
PHILLIP GAMBEL, PH.D.
PRIMARY EXAMINER

TECH CENTER 1600
4/22/02 ✓